

§ 113.114

for such fraction(s) that has been shown to be antigenic or immunogenic in accordance with paragraph (c)(2)(iv)(A) of this section.

[57 FR 38756, Aug. 27, 1992, as amended at 59 FR 67616, Dec. 30, 1994; 64 FR 43044, Aug. 9, 1999; 67 FR 15714, Apr. 3, 2002]

§ 113.114 Tetanus Toxoid.

Tetanus Toxoid shall be produced from a culture of *Clostridium tetani* which has been inactivated and is nontoxic. The toxoid may be either absorbed, precipitated, or purified and concentrated. Each serial of biological product containing *tetanus toxoid* fraction shall meet the applicable requirements in § 113.100 and shall be tested for purity, safety, and potency as prescribed in this section. A serial or subserial found unsatisfactory by any prescribed test shall not be released.

(a) *Purity test.* Final container samples of completed product from each serial and subserial shall be tested for viable bacteria and fungi as provided in § 113.26.

(b) *Safety test.* Bulk or final container samples of completed product from each serial shall be tested for safety as provided in § 113.33(b).

(c) *Potency test.* Bulk or final container samples of completed product from each serial shall be tested for potency. A group of 10 guinea pigs consisting of an equal number of males and females weighing 450 to 550 grams shall each be injected subcutaneously with 0.4 of the largest dose recommended on the product labels.

(1) Six weeks after injection, all surviving guinea pigs shall be bled and equal portions of serum, but not less than 0.5 ml from each, shall be pooled. For a valid test, the pool shall contain the serum from at least eight animals.

(2) The antitoxin titer of the pooled serum shall be determined in antitoxin units (A.U.) per ml using an enzyme-linked immunosorbent assay method acceptable to the Animal and Plant Health Inspection Service.

(3) If the antitoxin titer of the serum pool is at least 2.0 A.U. per ml, the serial is satisfactory. If the antitoxin titer of the serum pool is less than 2.0 A.U. per ml, the serial may be retested by the following procedure: *Provided,*

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That, if the serial is not retested, it shall be declared unsatisfactory.

(4) For serials in which the serum pool contains less than 2.0 A.U. per ml, the individual serum that constituted the pool may be tested by the enzyme-linked immunosorbent assay. If at least 80 percent of the individual serums have an antitoxin titer of at least 2.0 A.U. per ml, the serial is satisfactory. If less than 80 percent of the individual serums have an antitoxin titer of at least 2.0 A.U. per ml, the serial may be retested in 10 guinea pigs using the procedure described in (c)(1) and (2) above. The antitoxin titer of the pooled serum from the guinea pigs used in the retest shall be averaged with the antitoxin level of the pooled serum from the initial test. If the average of the two pools is at least 2.0 A.U. per ml, the serial is satisfactory. If the average of the two pools is less than 2.0 A.U. per ml, the serial is unsatisfactory and shall not be retested further.

[39 FR 16862, May 10, 1974, as amended at 46 FR 23224, Apr. 24, 1981; 50 FR 24905, June 14, 1985. Redesignated at 55 FR 35562, Aug. 31, 1990, as amended at 56 FR 37827, Aug. 9, 1991; 56 FR 66785, Dec. 26, 1991]

§ 113.115 *Staphylococcus Aureus* Bacterin-Toxoid.

Staphylococcus Aureus Bacterin-Toxoid shall be prepared from toxoided broth cultures of selected toxogenic strains of *Staphylococcus aureus* which has been inactivated and is nontoxic. Each serial of biological product containing *Staphylococcus Aureus* Bacterin-Toxoid shall meet the applicable requirements in § 113.100 and shall be tested for purity, safety, and potency as prescribed in this section. A serial found unsatisfactory by any prescribed test shall not be released.

(a) *Purity test.* Final container samples of completed product from each serial shall be tested for viable bacteria and fungi as provided in § 113.26.

(b) *Safety test.* Bulk or final container samples of completed product shall be tested for safety as provided in § 113.33(b). Also, the rabbits used in the potency test provided in paragraph (c) of this section shall constitute an additional safety test. If unfavorable reactions attributable to the product occur